

Claim 32 (New): A pharmaceutical composition which comprises the combined mixture of Claims 14 or 15 in combination with a pharmaceutically acceptable carrier, excipient or dilutant.

Claim 33 (New): The composition of Claim 32 in the form of a capsule, tablet, liquid or powder.

Claim 34 (New): A method for reducing serum cholesterol in human subjects which comprises administering to said subjects an effective amount of the composition of Claim 31.

Claim 35 (New): A method for reducing serum cholesterol in human subjects which comprises administering to said subjects a pharmaceutically effective amount of the composition of Claim 32.

REMARKS:

The Examiner's Office Action has been reviewed and considered, and revised claims are submitted in light of the Examiner's comments.

Applicant has deleted all non-allowed claims, i.e., Claims 1-9, and has added new Claims 13-35. In view of the amendments and differences with Applicant's invention, Applicant respectfully submits that the cited references do not singularly or in combination teach, suggest or anticipate the present invention. First, the policosanol claimed in the current invention is itself a novel composition of free or esterified sterols not claimed or disclosed by any prior art. Second, the composition claimed in the current invention is a novel composition of the policosanol (i.e. composition incorporating the policosanol) not claimed or disclosed by any prior art.

The present invention claims a policosanol whose composition is strikingly different from the policosanols disclosed in the cited references or other prior art. The Applicant respectfully submits that the Examiner did not address the effective amount of the components comprising composition or mixture. Applicant contends that each of the cited references, both singularly and in combination, do not teach, suggest, or anticipate the present composition and that effective amounts of alyphatic alcohols. In fact, Applicant respectfully contends that the claimed compositions of cited references are more similar to one another than they are to Applicant's composition, particularly in that the cited references call for the presence of octacosanol, triacontanol, dotriacontanol, tetratriacontanol, and others that are not relevant to Applicant's invention. (See Table 1 below). This fundamental and significant difference differentiates Applicant's invention from Sorkin, Jr. ('393) and Perez ('354).

TABLE I:

**RANGE OF COMPOSITIONS IN WEIGHT % OF
POLICOSANOLS FROM DIFFERENT SOURCES**

| Alypathic Alcohols Name (Number) of carbon atoms in molecule | Plant Wax Alcohols | | Wood Alcohols Present Invention | |
|---|---|--|--|--------------------------|
| | Ricebran Wax US Pat. No. 5,952,393 | Beeswax US Pat. No. 6,225,354 | Tall Oil Pitch | Tall Oil Soap |
| Octadecanol (18) | 0 | 0 | 0 | 1-10 |
| Eicosanol (20) | 0 | 0 | 1-5 | 5-25 |
| Docosanol (22) | 1-1.6 | 0 | 5-30 | 20-60 |
| Tetracosanol (24) | 9.7-14 | 1-4 | 20-60 | 20-50 |
| Hexacosanol (26) | 8.9-12.7 | 7-12 | 15-50 | 1-5 |
| Heptacosanol (27) | 0 | 1-4 | 0 | 0 |
| Octacosanol (28) | 16.9-24.3 | 30-60 | 0 | 0 |
| Nonacosanol (29) | 0 | 2-5 | 0 | 0 |
| Triacontanol (30) | 25.3-36.3 | 16-26 | 0 | 0 |
| Dotriacontanol (32) | 14.1-20.2 | 13-22 | 0 | 0 |
| Tetratriacontanol (34) | 6.7-9.6 | 2-6 | 0 | 0 |
| Hexatriacontanol (36) | 1.5-2.2 | 0 | 0 | 0 |

The Examiner also relies on Sorkin ('393), Maurel et al ('924) and Perez ('354) and that Applicant's claims are rejected for obviousness in that Maurel teaches the utilization of plant sterols. However, Applicant respectfully submits that even with the contention that Maurel teaches the utilization of plant sterols, the combination of Sorkin, Maurel, and Perez does not render obvious the mixture and methods claimed in the amended claims of the Applicant in that the cited references neither singularly nor in their combination address the 1) unique composition of the policosanol of Applicant's invention or 2) the unique composition incorporating the policosanol.

In terms of the provisional double-patenting rejection, Applicant again respectfully requests that a determination be made on the merits of the present invention, as well as on 09/772,790, after which Applicant will, if necessary, make a terminal disclaimer.

It is Applicant's belief that this application is in a condition for allowance. An action so indicating is respectfully requested. If the Examiner believes that discussion of this application would be beneficial, the undersigned may be contacted at the telephone numbers indicated below.

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Respectfully submitted,



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